

CLAIMS

1. Pharmaceutical composition containing as active principles Vitamin D associated to a calcium salt characterized in that it comprises a binding agent chosen in the group consisting of: propylene glycol, a polyethylene glycol presenting a molecular weight comprised between 300 and 1500, liquid paraffin or silicone oil and that the Vitamin D is present at the rate of 1 - 2 g of calcium for 500 1000 I.U. of Vitamin D.

2. Pharmaceutical composition according to Claim 1, in which the calcium used is in the form of a salt chosen in the group consisting of: phosphate, glycerophosphate, carbonate, bicarbonate, lactate, citrate, tartrate, gluconate, and chloride.

3. Pharmaceutical composition according to Claims 1 and 2, in which the calcium salt is calcium phosphate.

4. Pharmaceutical composition according to Claim 3 wherein the calcium phosphate is 30 - 80% by weight calculated on the total composition.

5. Pharmaceutical composition according to Claim 1, in which the Vitamin D used is Vitamin D₂ (or ergocalciferol), Vitamin D₃ (or cholecalciferol), or one of their mixtures.

6. Pharmaceutical composition according to Claim 5, in which the vitamin used is Vitamin D₃.

7. Pharmaceutical composition (bag) according to Claim 1, containing the propylene glycol or polyethylene glycol in a quantity comprised between 5-15% by weight calculated on the total composition.

8. Pharmaceutical composition (tablet) according to Claim 1, containing liquid paraffin or silicone oil.

9. Pharmaceutical composition according to Claim 7, characterized as follows:

Tribasic calcium phosphate	3.100 g
(corresponding to 1200 mg of Ca ⁺⁺)	
Cholecalciferol (Vit. D ₃) 100 000 IU/g	0.008 g
(corresponding to 800 IU)	
Propylene glycol	0.800 g
E110	0.002 g

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8	Colloidal silica	0.120 g
9	Lemon flavouring	0.100 g
10	Microcrystalline cellulose - MCC	0.200 g
11	Sodium saccharin	0.015 g
12	Anhydrous citric acid	0.165 g
13	Sucrose monopalmitate	0.120 g
14	Mannitol q.s. to	7.000 g

1 10. Pharmaceutical composition according to Claim 7, characterized as follows:

2	Tribasic calcium phosphate	3.100 g
3	(corresponding to 1200 mg of Ca ⁺⁺)	
4	Cholecalciferol (Vit. D ₃) 100 000 IU/g	0.008 g
5	(corresponding to 800 IU)	
6	Polyethylene glycol 400	0.800 g
7	E110	0.002 g
8	Colloidal silica	0.120 g
9	Lemon flavouring	0.100 g
10	Microcrystalline cellulose - MCC	0.200 g
11	Sodium saccharin	0.015 g
12	Anhydrous citric acid	0.165 g
13	Sucrose monopalmitate	0.120 g
14	Mannitol q.s. to	7.000 g

1 11. Pharmaceutical composition according to Claim 8, characterized as follows:

2	Tribasic calcium phosphate	3.100 g
3	(corresponding to 1200 mg of Ca ⁺⁺)	
4	Cholecalciferol (Vit. D ₃) 100 000 IU/g	0.008 g
5	(corresponding to 800 IU)	
6	Liquid paraffin	0.500 g
7	Sodium carboxymethyl cellulose	0.050 g
8	Sodium saccharin	0.015 g
9	Orange flavouring	0.100 g
10	Sorbitol q.s. to	4.400 g

1 12. Pharmaceutical composition according to Claim 8, characterized as follows:

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2	Tribasic calcium phosphate	3.100 g
3	(corresponding to 1200 mg of Ca^{++})	
4	Cholecalciferol (Vit. D ₃) 100 000 IU/g	0.008 g
5	(corresponding to 800 IU)	
6	Silicone oil	0.500 g
7	Sodium carboxymethyl cellulose	0.050 g
8	Sodium saccharin	0.015 g
9	Orange flavouring	0.100 g
10	Sorbitol q.s. to	4.400 g

1 13. Process for the preparation of a pharmaceutical composition according to
2 Claims 1 and 7, characterized by the following steps:

3 a) In a granulator turning at high speed, distribute the binding agent, consisting
4 of propylene glycol or low-molecular-weight polyethylene glycols over the calcium
5 salt.

6 b) Add the colloidal silica, approximately 25% of the mannite, the citric acid, and
7 the sodium saccharin, and mix for the time required and at the appropriate speed.

8 c) Add the mixture, prepared separately, consisting of sucrose palmitate, a
9 suspending agent, flavouring, colouring agent, the remaining part of the mannite,
10 and the Vitamin D₃, and mix together with the rest of the preparation.

11 d) Distribute the granulate thus obtained into bags.

1 14. Process for the preparation of a pharmaceutical composition according to
2 Claims 1 and 8, characterized by the following steps:

3 a) In a granulator turning at high speed, distribute the binding agent, consisting of
4 liquid paraffin or silicone oil, over the calcium salt.

5 b) Add in order, to a mixture of colloidal silica, carboxymethyl cellulose and
6 sodium saccharin previously sifted, the Vitamin D₃ and the sorbitol, mixing
7 thoroughly every time before a new ingredient is added. Pour the mixture into the
8 rotating granulator and mix for the required time and at the appropriate speed.

9 c) Compress the granulate to the required weight to obtain the desired tablets.

1 15. Composition according to Claim 1, for use in the treatment of nutritional
2 deficiency of calcium and Vitamin D in the elderly, to reduce the loss of bone

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3 tissue linked to age and to prevent femoral fractures and other non-vertebral
4 fractures.

1 16. Composition according to Claim 1, for use in the prevention of osteoporosis
2 induced by treatment with corticosteroids.

1 17. Method for the treatment of nutritional deficiency of calcium and Vitamin D in
2 the elderly, to reduce the loss of bone tissue linked to age and to prevent femoral
3 fractures and other non-vertebral fractures, in which therapeutically effective
4 quantities of a composition according to Claim 1 are administered to the patient.

1 18. Method according to Claim 16 for the prevention of osteoporosis induced by
2 treatment with corticosteroids.

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